IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	David F. Davenport, *et al.*
Application No. 10/692,063	Filing Date: October 23, 2003
Title of Application:	Method And Composition For Feeding Mammals
Confirmation No. 7269	Art Unit: 1616
Examiner	Ernst V. Arnold

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Appeal Brief Under 37 CFR §41.37

Dear Sir:

A Notice of Appeal from the final rejection of Claims 25-38, 40-48, 50 and 51, all pending claims of U.S. Patent Application No. 10/692,063, being filed on July 22, 2008, Appellant accordingly files its Appeal Brief in connection with the appeal. A Claims Appendix is submitted herewith, as are Appendices related to evidence previously submitted and decisions related to the case.

(i) Real Party In Interest

The real party in interest is MD's Choice, Inc., 2362 Airbase Road, Louisville, TN, 37777.

(ii) Related Appeals and Interferences

Appellant knows of no other prior or pending appeals, interferences, or judicial proceedings related to the instant Appeal.

(iii) Status Of Claims

Claims 1-24, 39, and 49 have been cancelled. Claims 25-38, 40-48, 50 and 51 stand rejected. Claims 25-38, 40-48, and 50 are the subject of the instant Appeal. A copy of each of these claims is attached hereto in the Claims Appendix.

(iv) Status Of Amendments

No Amendments have been filed since the outstanding Final Office Action was mailed on January 25, 2008.

(v) Summary Of Claimed Subject Matter

Claims 25 and 50 are the rejected independent claims and are discussed below.

Independent Claim 25

Claim 25 is directed toward a method for reducing energy deficit in a mammal having the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat with an effective proportion of components. (App. Par. [0015]). The composition includes a protein component that comprises whey powder and lactase in approximate effective proportion of between about 95% to about 100% by weight of whey powder, and between about 1% to about 5% by weight of lactase. *Id*.

Independent Claim 50

Claim 50 is directed toward a method for providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal having the step of administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat with an effective proportion of components. (App. Pars. [0015] and [0115]).

(vi) Grounds Of Rejection To Be Reviewed On Appeal

Claims 25 and 38-40 stand rejected under 35 U.S.C. §103(a) as unpatentable over Schlothauer et al. (WO 99/65326).

Claims 25-38, 40-43, 45-48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahmoud et al. (U.S. 5,104,676).

Claims 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahmoud et al. (U.S. 5,104,676) in further view of Hsia (U.S. 6,294,166).

(vii) Argument

Claims 25-38 and 40-48

Claim 25 requires a method for reducing energy deficit in a mammal that comprises the step of "enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat" and that the composition comprise "a protein component comprising whey powder and lactase in the following approximate effective proportions: between about 95% to about 100% by weight of whey powder, and between about 1% to about 5% by weight of lactase."

Schlothauer et al.

Schlothauer et al. discloses processes for preparing whey protein hydrolysate containing bioactive peptides. (Schlothauer et al., p. 3, l. 36-37). Schlothauer et al. disclose that this process includes the steps of "treating a whey protein containing substrate with one or more enzymes" and "terminating the hydrolysis before substantial production of bitter flavours." (*Id*. at p. 4, l. 1-4). Schlothauer et al. also disclose that the method can include the step of treating the substrate "with lactase and/or β-galactosidase, either before or during the whey protein hydrolysis, to hydrolyze lactose to galactose and glucose and synthesize galacto-oligosaccharides." (*Id*. at p. 4, l. 29-31). Schlothauer teaches that the administration of the disclosed composition reduces the blood pressure in a mammal. (*Id*. at p. 17, l. 13-36).

First, Schlothauer does not disclose administering whey powder but hydrolysed whey protein. The specification to the present Application notes that "[w]hey powder is typically a mixture of materials including, but not limited to lactose, protein, lactic acid and ash, and is one example of complex mixture that can be used as bulking agent. Whey (not whey protein concentrate) is a useful ingredient in an enteral feeding programs of mammals." (App. Par. [0049]). Schlothauer, on the other hand, discloses

administering hydrolysed whey protein. Schlothauer itself notes the distinction between the two. (See e.g. Schlothauer et al. at p. 1, l. 17-22).

Second, Schlothauer et al. does not disclose a method "for reducing energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount" of a composition having less than 3% fat. Schlothauer et al. simply discloses that the disclosed compositions are incorporated in functional foods and that the disclosed composition can be effective in lowering systolic blood pressure. (*See Id*. at p. 3, l. 25-29, Examples 6-10 and 16). In such functional foods, the disclosed hydrolysed whey protein is only a component of an overall food product and Schlothauer et al. does not disclose inherently or otherwise that the food product has less than 3% fat. As a result, Schlothauer et al. does not disclose administering the disclosed hydrolysed whey protein in a composition with less than 3% fat to a mammal with an energy deficiency, let alone in an "energy promoting effective amount." The Examiner asserts that the compositions in Schlothauer et al. intrinsically provide energy. (Final Office Action at page 4). However, this does not mean that Schlothauer et al. discloses administering to a mammal with an energy deficiency an energy promoting effective amount of the claimed composition.

Third, Schlothauer et al. fails to disclose that the composition comprises a protein component that comprises between about 1% to about 5% by weight of lactase. The Examiner identifies Examples 4 and 11 of Schlothauer et al. as satisfying this limitation. However, these examples and Schlothauer et al. in its entirety only disclose that lactase is used to hydrolyze lactose to galactose and glucose prior to a composition being administered to a mammal. Schlothauer does not disclose administering the hydrolysed whey protein to a mammal along with lactase. As a result, Schlothauer et al. does not disclose administering a composition that comprises whey powder and lactase, let alone a composition that comprises between about 1% to about 5% by weight of lactase.

Mahmoud et al.

Mahmoud et al. discloses a weight control product, the composition of which is shown in Table III. (Mahmoud et al. at col. 6, l. 17-60).

First, as shown in Table III, whey powder is not a component of the administered product. The Examiner states that "Mahmoud et al. teach using non-fat milk and whey powder and whey protein concentrate." (Final OA at p. 8). However, the identification of whey powder and whey protein concentrate are not components of the disclosed composition. They are elements of other weight control products, the composition of which are not disclosed. (Mahmoud et al. at col. 7, l. 13-19; col. 8, l. 35-40).

Second, Mahmoud et al. does not disclose a method "for reducing energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount" of a composition having less than 3% fat. Mahmoud et al. only discloses that the composition can be a meal replacement, up to 2 meals or 2 meals and 2 snacks a day, for a person looking to control their weight. (*See* Mahmoud et al. at col. 6, l. 62 – col. 7, l. 5). Mahmoud et al. does not disclose that the weight control product is administered to a mammal with an energy deficit.

Third, Mahmoud et al. fails to disclose that the weight control product comprises a protein component that comprises between about 1% to about 5% by weight of lactase. Mahmoud et al. discloses that the product of Table III is made by a process that includes combining non-fat dry milk with enzyme lactase. (*Id.* at col. 2, l. 41 - col. 4, l. 15). Like Schlothauer et al., Mahmoud et al. disclose that enzyme lactase is combined with non-fat dry milk or condensed skim milk to hydrolyze the lactose. (*Id.* at col. 4, l. 29-33). However, as shown in Table III, lactase is simply a component used in the process for making the product, but is it not included in the product that is administered to the mammal.

35 U.S.C. 103(a)

Applicants respectfully submit that Claim 25 is not obvious in view of Schlothauer et al. or Mahmoud et al. because these references fail to disclose each and every element of claim 25. It is well settled that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As discussed above, both Schlothauer et al. and Mahmoud et al. are missing a number of elements of claim 25. These references fail to disclose: 1) administering a composition with whey powder; 2) administering a composition with lactase; and 3) providing an energy promoting effective amount of a composition with less than 3% fat to a mammal with an energy deficit. These required steps and compositions are simply not disclosed by the cited references and as a result, do not provide a basis to conclude that one skilled in the art would combine or modify these references in accordance with claim 25. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) ("it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does"). The only reference

The Examiner asserts that one skilled in the art would be motivated to modify Schlothauer et al. in accordance with the claim 25 because this reference teaches "that a nutritional whey protein drink has the health advantages of whey protein. The determination of the amount of lactase to be added to the whey is deemed merely a matter of routine optimization, which one of ordinary skill in the art can perform during ordinary laboratory experimentation." (Final Office Action at p. 5). The Examiner further asserts that "[f]rom the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention." (Final Office Action at p. 5).

The Examiner asserts that one skilled in the art would modify Mahmound et al. in accordance with the claim 25 "to make a food product containing lactase and whey

powder and administer it to a subject as taught by Mahmoud et al. and reduce their energy deficit and product [sic] the instant invention. Mahmound et al. clearly teach introducing calories into the participant and therefore reducing their energy deficit. It is an intrinsic aspect of the method." (Final Office Action at p. 10).

However, as noted above, both Schlothauer et al. and Mahmound et al. are completely silent with respect to providing an energy promoting effective amount of a composition with less than 3% fat, let alone administering such a composition to a mammal with an energy deficit. Further, the Examiner's conclusion that one skilled in the art would perform the claimed method and include lactase in the administered composition is in fact contradicted by both Schlothauer et al. and Mahmound et al. Simply put, there is no evidence of record that supports the Examiner's assertion that one skilled in the art would modify the methods disclosed in Schlothauer et al. and Mahmound et al. to correspond to claim 25, let alone that one skilled in the art would have an expectation of success in performing the claimed method. Applicants respectfully submit that Examiner's conclusions are simply an improper application of ex post reasoning. *KSR*, 127 S.Ct. at 1742 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.")

In view of the foregoing, Applicants respectfully submit that Claim 25 is not obvious in view of Schlothauer et al. and Mahmound et al.

Claim 50

Claim 50 provides a method of "providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal" by "administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat…" As a

result, this claim requires that a mammal with an energy deficit be provided with a diet that consists of a feeding program and that the feeding program consists of a composition having less than 3% fat.

In rejecting this claim, the Examiner does not identify where Mahmoud et al. disclose these requirements or provide a reason why it would be obvious to modify the Mahmoud et al. method in accordance with Claim 50. The Examiner notes that "Mahmoud et al. teach that participants in a weight loss program may use the invention as a daily replacement for two meals…" (Final OA at p. 8). However, Mahmoud et al. does not disclose administering a diet that consists of a critical care feeding program with a composition that has less than 3% fat. Mahmoud et al. only disclose that the composition can be a meal replacement, up to 2 meals or 2 meals and 2 snacks a day. (Mahmoud et al. at col. 6, l. 62 – col. 7, l. 5; col. 7, l. 53-57). The Examiner's rejection does not address this requirement and does not provide a factual basis for concluding that one skilled in the art would modify the method in Mahmoud et al. in accordance with claim 50. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) ("it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does").

Further, Mahmoud et al. does not provide any basis to conclude that one skilled in the art would modify the disclosed method and limit the diet of a mammal to the product described in Table III. In fact, Mahmoud et al. teaches away such a requirement. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). As noted above, Mahmoud et al. teaches that the disclosed weight control product can replace up to 2 meals or 2 meals and 2 snacks a day. Such a disclosure teaches one skilled in the art that the disclosed weight control product can replace some portion of a mammal's diet, but the mammal's diet does not consist of the weight control product. As a result, Mahmoud et al. discourages one skilled in the art from modifying the disclosed method in accordance with claim 50.

The present Application provides a method for providing critical care to a mammal with an energy deficiency. The specification of the present Application provides a specific example of the claimed method providing critical care to a mammal:

> A 6 year old, 100 kg, American Miniature Horse presented to the Veterinary Teaching Hospital with a 3 day history of anorexia, depression, and ventral edema. She was nursing a healthy five week old foal at the time of presentation. Initial physical examination showed weakness, reluctance to move, elevated pulse and respiratory rate, and ileus. CBC and blood chemistry profile showed azotemia, hypocalcemia, metabolic acidosis, and elevated liver enzymes and total bilirubin. A serum triglyceride concentration was greater than 2000 mg/dl. Based on the above findings a diagnosis of hyperlipemia and hepatic lipidosis was made. Initial treatment consisted of intravenous polyionic fluids to correct the azotemia and provide maintenance fluids. Intravenous dextrose was provided to correct the negative energy balance. Subcutaneous heparin and insulin were given to treat the hyperlipemia. Despite aggressive medical therapy, the mare developed signs of hepatoencepalopathy including circling, muscle fasciculations and severe depression, corresponding to elevated blood ammonia. On day 2 of hospitalization, a nutrition consultation was performed. A three-stage ration was formulated based on the mare's requirements for digestible energy, crude protein, calcium, and magnesium for maintenance and lactation. The predetermined diet was low in fat and protein, but provided enough calories to decrease the utilization of body fat. The diet was delivered through a small-bore nasogastric tube every 2-4 hours. Each stage was given for 24 hours and by the third day of oral feedings the neurologic signs had disappeared and the serum triglyceride concentration had decreased to within normal range. The liver enzymes and total bilirubin

> were also decreasing. She began eating on day six of hospitalization and the enteral feedings were discontinued. She was discharged on day 8 after presentation with instructions to provide supplemental feedings for the next 3 weeks and to wean the foal to decrease the energy demands on the mare. A follow-up visit performed 4 weeks after discharge showed no significant abnormalities on physical examination and a continued decrease in the serum concentration of liver enzymes. (App. Par. [0115]).

Providing a diet that consists of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat decreases "hepatic lipidosis and the amount of processing the liver must perform to make energy available to somatic cells." (App. Par. [0103]). "The total program has a fat content of less than 3% so that it can be used in the face of compromised (or underdeveloped) liver function." (App. Par. [0106]). Further, this diet enables practitioners to "target specific needs and metabolic conditions. Providing a low fat nutraceutical composition has been found to improve the long-term prognosis for recovery and can be done both simply and cost effectively." (App. Par. [0006]). This is not taught, suggested or recognized by Mahmoud et al. and Mahmoud et al. does not provide a basis to conclude that one skilled in the art would modify the method in Mahmoud et al. to correspond to the Claim 50.

In view of the foregoing, Applicants respectfully submit that Claim 50 is not obvious in view of Mahmoud et al.

Conclusion

For the foregoing reasons, Applicant respectfully submits that the claimed invention embodied in each of claims 25-38, 40-48, 50 and 51 is patentable over the cited prior art. As such, Appellant respectfully requests that the rejections of each of claims 25-38, 40-48, 50 and 51 be reversed and the Examiner be directed to issue a Notice of Allowance allowing each of claims 25-38, 40-48, 50 and 51.

Respectfully submitted,

/ Wesley W. Whitmyer, Jr./

August 19, 2008

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Claims Appendix
to Appeal Brief Under 37 CFR §41.37
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1-24 (canceled)

25. A method for reducing energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components;

wherein the composition comprises a protein component comprising whey powder and lactase in the following approximate effective proportions: between about 95% to about 100 % by weight of whey powder, and between about 1% to about 5 % by weight of lactase.

26. The method of claim 25 wherein the composition comprises between about 2% to about 2.5% fat by weight.

27. The method of claim 25 wherein the composition comprises a nutrient component further comprising at least one ingredient selected from the group consisting of vitamin, mineral, trace mineral, antioxidant, amino acid and combinations thereof.

28. The method of claim 25 wherein the composition comprises a nutrient component further comprising liquid vitamin.

29. The method of claim 25 wherein the composition comprises a nutrient component comprising at least one vitamin selected from the group consisting of vitamin A, vitamin B-1, vitamin B-2, vitamin B-3, vitamin B-6, vitamin B-12, vitamin C, vitamin D-3, vitamin E, vitamin K, biotin, choline, folic acid, and combinations thereof.

30. The method of claim 25 wherein the composition comprises a nutrient component comprising at least one antioxidant selected from the group consisting of CoQ10, pantothenic acid, DMG, grape seed extract, bioflavinoid, inositol, PABA, citrus bioflavonoid, pyctogen, and combinations thereof.

31. The method of claim 25 wherein the composition comprises a feed component further comprising at least one ingredient selected from the group consisting of alfalfa, oats, and combinations thereof.

32. The method of claim 25 wherein the composition is in an oral liquid dosage form, or a powder form.

33. The method of claim 25 wherein said mammal is a human, horse, dog, cow, pig, goat, or sheep.

34. The method of claim 25 wherein the composition comprises a nutrient component comprising at least one mineral selected from the group consisting of calcium, magnesium, potassium, boron, molybdenum, vanadium and combinations thereof.

35. The method of claim 34 wherein the mineral is in amino acid chelate form.

36. The method of claim 25 wherein the composition comprises a nutrient component comprising at least one trace mineral selected from the group consisting of iron, copper, zinc, manganese, chromium, iodine, selenium, and combinations thereof.

37. The method of claim 36 wherein the mineral is in amino acid chelate form.

38. The method of claim 25 wherein the composition comprises at least one ingredient selected from the group consisting of whey powder, lactase, and combinations thereof.

39. (cancelled)

40. The method of claim 38 wherein the whey powder is smaller than about 45 mesh.

41. The method of claim 38 wherein the composition further comprises at least one monosaccharide.

42. The method of claim 41 wherein the monosaccharide is selected from the group consisting of glucose, galactose, fructose, and combinations thereof.

43. The method of claim 25 wherein the composition comprises a nutrient component comprising at least one amino acid selected from the group consisting of alanine, arginine, aspartic acid, cystine, glutamic acid, proline, glycine, histidine, hydroxyproline, isolcucine, leucine, lysine, methionine, phenylalanine, serine, threonine, tryptophan, tyrosine, valine, and combinations thereof.

44. The method of claim 25 wherein the composition comprises a functional food component further comprising at least one ingredient selected from the group consisting of glucosamine, salt, amino acid, yeast, fermentation extract, and combinations thereof.

45. The method of claim 44 wherein the glucosamine is a chemical selected from the group consisting of glucosamine sulphate, glucosamine sulfate 2KCL, glucosamine sulfate NaCl, glucosamine hydrochloride, N-acetylglucosamine, Poly-Nag. glucosamine, and combinations thereof.

46. The method of claim 44 wherein the salt is sodium chloride.

47. The method of claim 44 wherein the amino acid is selected from the group consisting of L-glutamine, L-arginine, carnitine, and combinations of these.

48. The method of claim 44 wherein the fermentation extract comprises at least one ingredient selected from the group consisting of prebiotic, probiotic, synbiotic, and combinations thereof.

49. (cancelled)

50. A method for providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal comprising the step of administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components.

51. A method for maintaining health in a mammal comprising the step of administering to the mammal an effective amount of a composition having less than 3% fat comprising an effective proportion of components;

wherein the composition comprises a feed component comprising a non-soluble fiber.

Evidence Appendix
to Appeal Brief Under 37 CFR §41.37
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No evidence, including evidence submitted under 37 CFR 1.130, 1.131 or 1.132, has been entered by the Examiner and relied upon by Appellant in the appeal.

Related Proceedings Appendix
to Appeal Brief Under 37 CFR §41.37
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There are no related Appeals or Interferences. As such, there are no decisions rendered by a court or the Board in any such Appeals or Interferences.